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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,488	05/25/2001	Anthony E. Bolton	033136-179	4401

7590

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 11/19/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,488

Applicant(s)

BOLTON ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-45 is/are pending in the application.
- 4a) Of the above claim(s) 31-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7, 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

There was no restriction in this case because all of the original claims 1-18 were drawn to "use" claims and treated as method claims, and now replaced by claims 19-30, drawn to method (see page 7, 3rd and 4th paragraphs of the Amendment, Paper No. 9). Newly submitted claims 31-45 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 31-45 are drawn to a composition and claims 19-30 are drawn to method of treatment. The invention drawn to the composition corresponding to claims 31-45 and the invention drawn to method of treatment corresponding claims 19-30 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product could be used in method of treating endothelial dysfunction.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. The search required for each of the above inventions is not coextensive with regard to the literature and the sequence searches. Further, a reference which would anticipate the invention of any one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons, restriction for examination purposes is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claims 31-45, drawn to an nonelected invention. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 19-45 are pending and claims 19-30 are examined on merits.

Claim Rejections - 35 USC § 112

Rejection of claims 1-18 (replaced by new **claims 19-30**) **remain rejected** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites "T-cell-mediated or inflammatory disorders" and applicant argues that the newly added independent claim 19 lists specific diseases, therefore defining metes and bounds of "T-cell-mediated or inflammatory disorders". However, contact hypersensitivity (CHS) that the specification at page 13 lines 5 says is a preferred embodiment of the present invention is not included in the lists of the diseases and at least three diseases that belong to "T-cell-mediated or inflammatory disorders" also belong to endothelial dysfunction (see rejection of claim 19 under double patenting below) and it is still not clear what is being claimed for patent protection by the limitation "T-cell-mediated or inflammatory disorders".

main text

Rejection of claims 1-18 (replaced by **new claims 19-30**) **remain rejected** for reasons set forth at the paragraph bridging pages 3-5 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of treating CHS, does not reasonably provide enablement for any other diseases listed in claim 19. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims are drawn to a method of treating various diseases applicant termed as "T-cell-mediated or inflammatory disorders". The "T-cell-mediated or inflammatory disorders" include rheumatoid arthritis and multiple sclerosis and the art recognizes that treating such diseases is not a trivial matter.

Applicant argues that producing appropriate apoptotic bodies for any of the specific disease is well known in the art and applicant further argue at the paragraph bridging page 10 and 11 that one in skilled in art would know which apoptotic bodies are best suited for treating the different disorders recited by the claimed claims, and CHS in

Example 1 is a well known standard method for investigating inflammation, inflammatory cytokines are implicated in the various diseases listed in the claims, therefore the instant claims are enabled.

These arguments have been fully considered but found not persuasive because teaching of the specification is limited to method of treating mice with CHS, which is not a model for multiple sclerosis, rheumatoid arthritis, or any other disease listed in the instant claims. Applicant's argument that producing appropriate apoptotic cells for each of specific diseases in instant claim 19 is well known in the art is not convincing because the art recognizes that apoptotic cells are not accepted treatment for any of the specific diseases listed in the claim 19. It might take years through lengthy clinical trials for research clinicians to determine (1) which source of the cells to make apoptotic cells and/or apoptotic bodies for each of specific diseases, (2) a specific dose for any one of the diseases listed in the instant claims. Many of the diseases listed in claim 19 are notoriously difficult to treat, and therefore those skilled in the art would have reason to doubt unsupported assertions of successful treatment methods for those diseases.

Double Patenting

Claim 19 (corresponding to now cancelled claim 11) provisionally **remain rejected** for the reason set forth at page 6 of the previous Office Action under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 09/866,569. Applicant argues since the phrase "T-cell-mediated or inflammatory disorders" and "endothelial dysfunction" are different, they are different inventions: instant claims are directed to method of treatment or prophylaxis of T-cell-mediated or inflammatory disorders (examples of such diseases include **atherosclerosis, inflammatory bowel disease, and graft versus host disease**) and the claim in copending Application No. 09/866,569 is directed to method of treatment or prophylaxis of endothelial dysfunction ((examples of such diseases include atherosclerosis, **inflammatory bowel disease, and graft versus host disease**)). Applicant is requested to note that both claims are directed to method of treating same diseases with same product. This is a provisional obviousness-type

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double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Misook Yu

November 12, 2002

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